IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA ex rel. SHANTAE M. WYATT and LATOYA SPARROW, Plaintiffs, v. BIOTEK REMEDYS, INC, CHAITANYA R. GADDE, CARLA SPARKLER, and DR. DAVID TABBY, Defendants.	Civil Action No. 19-CV-6069-PD

UNITED STATES' COMPLAINT IN INTERVENTION

By notice to the Court on May 3, 2021, the United States filed its Notice of Intervention in part in the above-captioned case. The United States alleges as follows:

INTRODUCTION

1. The United States of America ("United States") brings this action pursuant to the False Claims Act, 31 U.S.C. §§ 3729-33 ("FCA"), seeking treble damages and civil penalties, for losses sustained by the Medicare Program as a result of fraudulent kickback schemes orchestrated by specialty pharmacy BioTek reMEDys, Inc. ("Biotek"), Chaitanya R. Gadde ("Gadde"), Carla Sparkler ("Sparkler"), (collectively, the "Biotek Defendants"), and Dr. David Tabby ("Tabby"). Under these schemes, the Biotek Defendants paid kickbacks to patients and physicians, most notably Tabby, to ensure a steady stream of patient referrals to Biotek.

2. The federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) ("AKS"), expressly prohibits an individual or entity from offering, paying, soliciting, or receiving any "remuneration," which means anything of value, to "any person to induce such person" to purchase or recommend a drug or service covered by Medicare. Over 25 years ago, the

government warned companies like Biotek that routine waivers of the cost-sharing amounts of Medicare beneficiaries, without regard to authenticated financial need, could constitute illegal remuneration under the AKS. 59 Fed. Reg. 65373, 65374 (Dec. 19, 1994) ("1994 Special Fraud Alert").

3. In spite of the long-standing knowledge that such conduct could violate the AKS, the Biotek Defendants, from no later than August 2015 through at least May 2020 ("relevant time period"), knowingly and willfully waived patient copays to induce patient referrals, generating millions of dollars in revenue for Biotek.

4. As a specialty pharmacy, Biotek sells expensive infusion drugs and services. The Biotek Defendants understood that the high price of its drugs and the large accompanying Medicare copayments could deter many patients from purchasing those drugs in favor of less costly alternatives. The Biotek Defendants therefore devised a scheme to make the drugs "free" to patients by routinely waiving their Medicare copayments, irrespective of whether those patients were experiencing financial need, to induce patients to purchase drugs and services from Biotek, and to induce physicians to refer patients to Biotek in the first place.

5. But the Biotek Defendants did not stop there. To induce a steady stream of referrals, the Biotek Defendants also provided Tabby and other physicians with numerous other kickbacks, including expensive meals and gifts, as well as free administrative and clinical services. These clinical and administrative services saved these physicians, most notably Tabby, time and money, which helped them earn additional income, see more patients, and refer additional patients to Biotek.

6. The Biotek Defendants knew that their schemes were illegal. Biotek's own employees warned the Biotek Defendants about their illegal conduct. In fact, Biotek engaged in annual compliance training in which employees were informed about issues related to the AKS.

7. Nevertheless, the Biotek Defendants put their own greed above compliance with the law to enhance their profitable schemes. During the relevant time period, Biotek submitted and received reimbursement for over $34 million in false claims for prescriptions to Medicare Part D that were tainted by kickbacks and should not have been paid.

JURISDICTION AND VENUE

8. This action arises under the FCA, as amended, 31 U.S.C. §§ 3729-33, as well as the common law.

9. This Court has jurisdiction over this action under 31 U.S.C. § 3730(a), as well as 28 U.S.C. §§ 1331, 1345, and 1367(a).

10. The Court may exercise personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because each Defendant either resides or transacts business in this District, or committed proscribed acts in this District.

11. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) as well as 28 U.S.C. §§ 1391(b) and (c).

PARTIES

12. Plaintiff, the United States, brings this action on behalf of the U.S. Department of Health and Human Services ("HHS"), and, specifically, its operating division, the Centers for Medicare & Medicaid Services ("CMS").

13. Relator Shantae M. Wyatt is an individual who resides in the State of Delaware. Relator Wyatt was employed by Biotek from April 2018 until October 2019. Relator Latoya Sparrow is an individual who resides in the State of Delaware. Relator Sparrow was employed

by Biotek from March 2018 until September 2019. On December 23, 2019, Relators Wyatt and Sparrow filed *United States ex rel. Wyatt et al. v. Biotek Remedys, Inc. et al.*, Civil Action No. 19-CV-6069-PD (E.D. Pa.), pursuant to the *qui tam* provisions of the FCA, 31 U.S.C § 3730(b). Relators filed their Amended Complaint on March 10, 2021.

14. Defendant Biotek has its principal place of business in New Castle, Delaware. Biotek is a specialty pharmacy that, among other things, provides drugs, biologics, and infusion services to patients.

15. Defendant Chaitanya R. Gadde is an individual who resides in the State of Delaware. Gadde is the Chief Executive Officer of Biotek.

16. Defendant Carla Sparkler is an individual who resides in the State of New Jersey. Sparkler is the Chief Marketing Officer of Biotek.

17. Defendant Dr. David Tabby is an individual who resides in the Commonwealth of Pennsylvania. Tabby is a doctor of osteopathic medicine and is the owner of Optimum Neurology, which has its principal place of business in Bala Cynwyd, Pennsylvania.

LEGAL BACKGROUND

I. THE MEDICARE PART D PROGRAM

18. In 1965, Congress created the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 et seq. ("Medicare"). Congress established Medicare to provide health insurance coverage for people aged sixty-five or older and for people with certain disabilities or afflictions. *See* 42 U.S.C. §§1395 *et. seq.*

19. Medicare is funded by the federal government and administered by HHS through CMS.

20. In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. 108-173, 117 Stat. 2066, which established a voluntary prescription drug benefit program for Medicare enrollees, otherwise known as Medicare Part D. Under Medicare Part D, Medicare contracts with private entities, known as Plan Sponsors, to administer prescription drug plans. *See* 42 U.S.C. § 423.4.

21. Medicare beneficiaries who wish to receive Part D benefits must enroll in a Part D Plan offered by a Plan Sponsor. An individual is eligible to enroll in Medicare Part D if the individual lives in the service area of a Part D plan and is entitled to Medicare benefits under Medicare Part A or enrolled under Medicare Part B. *See* 42 U.S.C. § 423.30(a).

22. The Plan Sponsors are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Plan Sponsors, in turn, enter into subcontracts with pharmacies or other "downstream entities" to provide prescription drugs to the Medicare Part D beneficiaries enrolled in their plans.

23. These pharmacies and other downstream entities submit claims to Part D plans that pay for the drugs using funds provided by CMS from the Medicare Prescription Drug Account, which is an account within the Federal Supplementary Medical Insurance Trust Fund. *See* 42 U.S.C. § 423.315(a).

II. MEDICARE PART D COPAY OBLIGATIONS

24. By congressional design, under the Medicare statute, a Part D beneficiary may be required to make a partial payment for the cost of these prescription drugs in the form of a "copayment," "coinsurance," or "deductible" (collectively, "copays"). These copays can be substantial for expensive medications and vary throughout the year, depending on a beneficiary's total Part D covered expenses incurred that year up to that point. *See* 42 U.S.C. § 1395w-102. For example, after meeting an annual deductible ($445 in 2021), the standard Part D benefit

requires a 25 percent patient copay up to an "initial coverage limit" ($4,130 in 2021). *Id.* at b(1)-(2).

25. After meeting the "initial coverage limit," copays increase substantially until meeting an "annual out-of-pocket threshold" for the coverage year. This period between exceeding the "initial coverage limit" and before crossing the "annual out-of-pocket threshold" is referred to as the "coverage gap." *See* 42 U.S.C. § 1395w-102(b)(2)(D). For brand name drugs, the copays owed in the "coverage gap" were 100 percent through 2010, 50 percent in 2011 and 2012, 47.5 percent in 2013 and 2014, gradually declining to no more than 25 percent in 2021.

26. The financial thresholds for the "deductible," "initial coverage limit," and "annual out-of-pocket threshold" have increased each year since 2006 pursuant to a statutory and regulatory formula (from $250, $2,250, and $3,600, respectively, to $445, $4,130, and $6,550, respectively, in 2021).

27. Medicare Part D coverage for costs incurred after the "coverage gap," *i.e.*, on costs incurred for the remainder of the benefit year above the "annual out-of-pocket threshold" ($6,550 in 2021), is commonly referred to as "catastrophic coverage."

28. Congress determined that patients owe a copay in the "catastrophic coverage" phase that equals the greater of: (1) five percent of the prescription drug costs; or (2) a small fixed dollar amount ($3.70 for brand name drugs in 2021). *See* 42 U.S.C. § 1395w-102(b)(4). As a practical matter, a patient will owe a five percent copay in the "catastrophic coverage" phase of Part D for any expensive, brand name drug. The remaining costs are paid by a "reinsurance subsidy" from CMS (80 percent) and the Part D plans (15 percent).

29. Copays exist to encourage physicians and beneficiaries to be efficient consumers of federally reimbursed health care products, while also encouraging those manufacturing or

selling such products to price them based on market forces such as consumer sensitivity and competition. Companies circumvent this congressionally-designed check on health care costs when they waive or subsidize copays.

III. FALSE CLAIMS ACT

30. The FCA provides, in pertinent part, that any person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> . . . is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. § 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.[1]

31 U.S.C. § 3729(a)(1).

31. For purposes of the FCA, the terms "knowing" and "knowingly" mean that a person, with respect to information: (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud is required. 31 U.S.C. § 3729(b)(1).

32. The FCA defines the term "claim," in pertinent part, as

> any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or

[1] For violations occurring on or after November 2, 2015, the civil penalty amounts range from a minimum of $11,181 to a maximum of $22,363. 28 C.F.R. § 85.5.

> interest, and if the United States Government—(I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded[.]

31 U.S.C. § 3729(b)(2).

33. For purposes of the FCA, the term "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

IV. ANTI-KICKBACK STATUTE

34. The AKS, 42 U.S.C. § 1320a-7b(b), is a federal criminal statute that prohibits the knowing and willful payment of remuneration to induce or reward patient referrals or the generation of business involving any item or service payable by federal health care programs. The AKS covers both those who pay kickbacks as well as those who solicit or receive remuneration.

35. The AKS arose out of congressional concern that payoffs and kickbacks in federal health care programs would result in goods and services being provided that are excessively costly, medically unnecessary, of poor quality, or potentially harmful to patients. To protect the integrity of federal health care programs from these difficult-to-detect harms, Congress enacted a *per se* prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback gives rise to overutilization, poor quality of care, or patient harm. In particular, when determining what conduct to prohibit, Congress determined that the inducements at issue would "contribute significantly to the cost" of federal health care programs absent federal penalties as a deterrent. H.R. Rep. No. 95-393, at 53 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3039, 3056.

36. First enacted in 1972, Congress strengthened the AKS in 1977, 1987, and 2010, to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social

Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93; Patient Protection and Affordable Care Act, Pub. L. No. 111-148. In adopting and repeatedly strengthening the AKS, Congress sought to "strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the [M]edicare and [M]edicaid programs." H.R. Rep. No. 95-393, at 1 (1977).

37. In pertinent part, the AKS provides:

(b) Illegal Remunerations

> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind –
>
> > (A) in return for referring an individual to a person for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> >
> > (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> > (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

42 U.S.C. § 1320a-7b(b)(1) and (2).

38. The AKS defines remuneration to include anything of value, including "cash" and "in-kind" payments or rebates. 42 U.S.C. § 1320a-7b(b)(2). Money and other forms of financial subsidies that are used to pay or waive Medicare copays constitute remuneration under the AKS.

39. The AKS defines a "Federal health care program" to mean "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government," except for the health insurance program for federal employees under 5 U.S.C. §§ 8901 *et seq*. 42 U.S.C. § 1320a-7b(f). Medicare is a "Federal health care program" for purposes of the AKS.

40. The AKS provides that "[w]ith respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section." 42 U.S.C. § 1320a-7b(h).

41. The AKS further provides that any Medicare claim "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). Under this provision, claims submitted to federal health care programs that result from violations of the AKS are *per se* false or fraudulent within the meaning of 31 U.S.C. § 3729(a). Accordingly, a person violates the FCA when that person knowingly submits or causes to be submitted claims to federal health care programs that result from violations of the AKS.

42. Compliance with the AKS is material to the agency's decision to pay a Medicare claim.

43. At the time the claims at issue in this complaint were paid, Medicare was not aware of the Defendants' conduct that is described herein.

V. WAIVER OF COST SHARING OBLIGATIONS

44. Routine waivers of copays, without regard to authenticated financial need, may constitute illegal remuneration under the AKS. Indeed, as early as 1994, HHS Office of Inspector General ("HHS-OIG") issued a "Special Fraud Alert" regarding the unlawful practice of routinely waiving the cost-sharing amounts of Medicare beneficiaries, because such practices may violate the AKS and result in illegal inducements to beneficiaries and overutilization of healthcare items and services. 1994 Special Fraud Alert; *see* 42 U.S.C. § 1320a-7b(b). Specifically, HHS-OIG stated:

> At first glance, it may appear that routine waiver of copayments and deductibles helps Medicare beneficiaries. By waiving Medicare copayments and deductibles, the provider of services may claim that the beneficiary incurs no costs. In fact, this is not true. Studies have shown that if patients are required to pay even a small portion of their care, they will be better health care consumers, and select items or services because they are medically needed, rather than simply because they are free. Ultimately, if Medicare pays more for an item or service than it should, or if it pays for unnecessary items or services, there are less Medicare funds available to pay for truly needed services.

1994 Special Fraud Alert.

45. In identifying common patterns of fraudulent conduct, HHS-OIG provided a non-exhaustive list of problematic actions, including the routine use of "financial hardship" forms with no good faith attempt to determine the beneficiary's actual financial condition and the failure to collect copayments or deductibles for reasons unrelated to indigency. *Id.* at 65374.

46. The principles underlying the Special Fraud Alert have been applied in fashioning narrow statutory safe harbors that only permit copay waivers in certain narrow circumstances,

deemed to alleviate concerns of fraudulent inducements. Specifically, with regard to Medicare Part D programs, an entity may receive safe harbor protection under the AKS for waivers of cost-sharing amounts only where the entity or person waiving the copay (i) does not offer the waiver as part of any advertisement or solicitation; (ii) except for subsidy-eligible individuals, as defined in 42 U.S.C. § 1395w-114, does not routinely waive coinsurance or deductible amounts; and (iii) except for subsidy-eligible individuals, as defined in 42 U.S.C. § 1395w-114, determines in good faith that the recipient of the waiver is in financial need or fails to collect the owed amount after reasonable collection efforts. *See* 42 U.S.C. § 1320a-7b(b)(3)(G); 42 C.F.R. § 1001.952(k)(3); *see also Medicare Prescription Drug Benefit Manual,* ch. 5, § 30.4.

47. The safe harbor does not protect waiver of cost sharing that is "characterized as a 'cost-saving program'. . . [or] waivers that are advertised as part of a 'program' to waive copayments." 81 Fed. Reg. 88368, 88372 (Dec. 7, 2016).

THE DEFENDANTS' FRAUDULENT SCHEMES

I. The Biotek Defendants' Routine Waiver of Patient Copays

48. Biotek is a specialty pharmacy. Specialty pharmacies are distinct from traditional pharmacies in that specialty pharmacies provide medications requiring specialized handling, storage, and distribution for patients with complex disease states who require regular contact with and clinical management by practitioners. Biotek focuses much of its business on providing specialty drugs to patients through infusion therapy, which is the administration of a solution of medication intravenously, sometimes over the course of several hours. Biotek offers patients the option to receive infusion therapy services in their homes or at its infusion suite in Delaware.

49. The medications sold by Biotek can be expensive. For example, in 2020, Soliris, one of the drugs dispensed by Biotek, cost between $50,000 to $55,000 for a 28-day supply.

Octagam, another drug dispensed by Biotek, cost between $15,000 and $43,000 for a 28-day supply. Medicare patients prescribed these drugs may be required to pay thousands of dollars a year in copays.

50. The Biotek Defendants understood that high copays could deter patients from purchasing drugs from Biotek. Indeed, patients often expressed concern about their copays to Biotek. The Biotek Defendants, therefore, routinely waived copays, without requiring proof of financial hardship, to induce patients to purchase Biotek's drugs and to induce physicians, including Tabby, to refer their patients to Biotek in the first place.

51. The data reflects that from at least August 2015 through at least May 2020, the Biotek Defendants routinely waived copays for Medicare patients who had copays greater than $2,500. Of the 258 Medicare patients with copays greater than $2,500 who were treated by Biotek during this time, Biotek waived all, or substantially all, of the copays for 237 of those patients. These patients accounted for over $22 million in Part D revenue to Biotek.

52. The Biotek Defendants advertised the routine waiver of copays to patients so that the patients would purchase their drugs from Biotek. Chief Marketing Officer Sparkler instructed Biotek employees to inform patients during the intake process that Biotek would cover the copays. For example, in October 2017, a Biotek employee informed Sparkler that a new patient, D.P., was afraid of getting infusion treatment at Biotek because her copay would be "thousands of dollars." Thirteen minutes later, Sparkler replied: "TELL HER NOT TO WORRY! SHE WON'T HAVE ANY OOP!!! [out of pocket]." Sparkler also explained that she had been calling on that patient's physician for a while, and that she "need[ed] something to put me over the hump."

53. Intake employees also mentioned a "Biotek foundation" to patients that they alleged would cover the patients' copays, even though no such foundation existed. In fact, Biotek covered the patients' copays. For example, in February 2019, a Biotek employee explained that she spoke to a patient, G.R., during the intake process, and mentioned the "Biotek foundation" to the patient after the patient expressed concern about her copay.

54. The Biotek Defendants also advertised Biotek's routine waiver of copays and its nonexistent "Biotek foundation" to physicians to induce physicians to refer their patients to Biotek, as reflected in these call notes, which reflected discussions between Biotek sales representatives and the doctors they called upon:

a. "Dr. [H] hasn't written an IVIG script since February . . . [but has] us in mind for the next script as they have gotten patients that have issues with copayments."

b. Doctor "[w]as very interested in our foundation as she has an IVIG patient that is having issues with her copayment."

c. "Amy and Connie were interested in the . . . foundation."

d. "Told her about the Patient Asst. and sampling programs."

e. "Mentioned tetrabenezine and patient assistance program."

f. "Gave her BioTek speech, how we handle everything, insurance, payment, etc…"

55. Sparkler managed Biotek's relationships with many of its top referring physicians and assured her physicians that their patients would pay nothing out of pocket. For example, in an email dated October 30, 2017, Sparkler wrote that she had spoken to a physician about a

specific patient and "assured him about our foundation and any out of pocket expenses. . . .Let's get all these promises met!"

56. This was particularly true for Tabby, who was always assured by the Biotek Defendants, and Sparkler in particular, that his patients would pay nothing out of pocket. For example:

a. January 2016: Tabby asked Sparkler if Biotek had an infusion suite available for one of his patients who was concerned about the 20% insurance copay. Sparkler responded: "Let me talk to Chai…Honestly that's what we normally eat…"

b. February 2016: Sparkler discussed patient M.F.'s $500 copay with Tabby, and stated that if M.F. was treated in Biotek's infusion suite: "I can eat that $500…This conversation is BETWEEN US." Tabby responded, "Suite is fine. Thanks." Sparkler then ordered other Biotek employees: "DO NOT bill this patient for any monies due."

c. May 2016: Sparkler informed another Biotek employee that Tabby's patient, D.S., was concerned that he would be getting a bill from Biotek and stated: "Please assure him WE ARE NOT."

d. December 2017: Tabby informed Sparkler that patient C.G. "need[ed] co-pay help." Sparkler responded: "She should have Zero amount due with Biotek."

e. January 2019: Relator Sparrow informed Gadde and Sparkler that Biotek had a large number of outstanding copays that had not been collected, to which Sparkler replied: "If they are David Tabby patients . . . they are a write off."

f. January 2019: A Biotek employee wrote that they had never billed a certain patient, J.N., "due to her being a DR. TABBY patient."

57. From August 2015 through at least May 2020, Biotek fully waived the copays for almost 100 percent of Tabby's Medicare patients with copay balances above $2,500. In fact, of the over $300,000 in copays owed by Tabby's patients during the relevant time period, Biotek collected only $45.

58. The Biotek Defendants did not have a standardized process for verifying patient financial hardship and did not typically require proof of financial hardship before waiving copays. For example:

a. June 2016: A Biotek employee emailed Sparkler to discuss that a Medicare patient, B.E., was uncertain about getting home infusion therapy "due to the cost." The employee stated that she had spoken to Gadde, and that he was "willing to waive the copay if need be." Twenty minutes later, Sparkler informed Gadde and the employee that she had just spoken to the patient and that Biotek would "need to give her the grant so that she doesn't have any copay."

b. March 2017: A Biotek employee asked Sparkler whether Biotek would "eat the copay" for a Medicare patient, D.C., to which Sparkler replied: "Her bill should be Printed and 0 balance to the patient."

c. April 2017: One of Tabby's Medicare patients, S.M., refused to set up his infusion with Biotek because he was worried about his copay. Sparkler emailed Tabby and informed him that even if S.M. did not qualify for financial assistance, Gadde would have Biotek cover his copay.

d. July 2017: An employee informed Sparkler that a Medicare patient requested copay assistance. Sparkler replied: "We are guaranteeing the no out of pocket." Six minutes later, the employee informed Sparkler that she had "spoke[n] to the patient and updated him. I told him to fill out the paperwork in the mail and if he does not qualify he will be covered either way with no co-pay."

59. The Biotek Defendants did not require proof of financial need before waiving copays. For the 237 Medicare patients discussed above whose copays were waived between at least August 2015 and May 2020, Biotek either had no paperwork at all, or had incomplete documentation, for 52 percent of those patients. Over half of the paperwork justifying financial need for the remaining 48 percent of patients was produced well after those patients had begun service, and after Biotek had already begun to waive their copays. For example, Biotek waived one patient's copays 33 times over three years before it received a signed hardship form from the patient.

60. The Biotek Defendants did not make reasonable attempts to collect the copays from the vast majority of patients. Sparkler instructed employees not to collect copays, especially from patients referred by Tabby and the other physicians that Sparkler called on personally. In addition, the Biotek Defendants had an "alert" placed in its patient records system, CPR+, to notify employees not to bill the patients of Sparkler's preferred physicians, such as Tabby. For example, in a January 2017 email, Sparkler emailed a Biotek employee about a Tabby patient, stating that the patient "was not supposed to be getting balance billed." The Biotek employee responded: "[T]he Dr's name is in the alert so she is not getting billed."

61. On occasion, Biotek employees created invoices that purported to show collection efforts. Biotek, however, did not send the vast majority of those invoices to the patients. Rather, employees created invoices so that it appeared that Biotek was attempting to collect from the patients, and then wrote off the unpaid copays in the CPR+ system as "adjustments." For example, when Sparkler questioned one Biotek employee in January 2017 as to why a certain patient invoice had been created, the employee responded: "We have to look as though we are attempting to collect the copays, so we go through the process prior to writing it off."

62. The Biotek Defendants, and Gadde in particular, were well aware of the large amount of outstanding copays on Biotek's books. Gadde maintained detailed spreadsheets that noted the outstanding patient balances, which sometimes exceeded over a million dollars. Other Biotek employees also discussed these outstanding balances with Gadde and Sparkler. For example, in a January 2019 email, Relator Sparrow emailed Gadde, Sparkler, and other employees to discuss that Biotek had over $1.8 million in outstanding patient balances, including almost $200,000 outstanding for over 300 days.

63. The Biotek Defendants, however, were willing to waive the copays of Medicare patients because these patients were a lucrative source of Medicare Part D revenue for Biotek. For example, when a Biotek employee asked Sparkler in a March 2017 email about a Medicare patient, C.C., who was now in the catastrophic phase of coverage, Sparkler replied: "The 10,000 we made will Cover his out of pocket just fine." As summed up in a June 2016 email, Sparkler stated to Gadde: "On average all of our Part D plans we make about 40 to 50% profit each month – On the low side without a first dose these patients are worth about $24,000…Basically we don't make nearly the same amount of money we do on Private Insurances as we do with Medicare."

II. Sham Reform Efforts

64. Several employees, including Relators, informed Gadde that they believed Biotek's schemes were illegal. In addition, in January 2019, a Biotek compliance analyst informed Gadde that Biotek's internal risks included: a "lack of financial discussion with patient [or] a lack of clear documentation of the substance or specifics of those conversations;" "missed attempts to obtain the required financial assistance paperwork to complete the approval process;" and "significant time gaps between start of care and approval of financial assistance or hardship."

65. Shortly thereafter, in February 2019, the Biotek Defendants became aware of the United States' FCA settlement with Pentec Health[2] for violating the AKS by waiving patient copays. Gadde then convened an internal meeting at which multiple employees informed him that they had concerns about Biotek's compliance with the law. One supervisor wrote at the time: "I'm not sure if enough effort is being put in towards finding copay assistance or utilizing other options before offering Financial Hardship right away or digging a little deeper. . . .We've even had patients forwarded [for] hardship that actually said they would pay their bills."

66. In March 2019, Biotek created what one employee described as a "new hardship form that requires us to actually obtain copies of people's finances. Instead of just taking their word for it." Sparkler met with Biotek's employees and informed them that, going forward, Biotek would collect payments from patients who did not qualify for assistance. Biotek then sent letters to its patients informing them that it would now be billing for copays.

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[2] *Pentec Health, Inc. to Pay $17 Million to Settle False Claims Act Allegations* (February 9, 2019), https://www.justice.gov/usao-edpa/pr/pentec-health-inc-pay-17-million-settle-false-claims-act-allegations)

67. These letters, however, triggered emails and calls from patients and doctors, such as Tabby, questioning why Biotek suddenly was billing patients. For instance, one Biotek employee reported talking to a patient who stated that he had "never received a bill since he started with us in 2017 and wanted a reason why [he was] getting a bill now." Another patient sent an email stating that he was "shocked" to receive a bill when he had been "receiving [his] infusion medication FREE from your company for years."

68. Instead of collecting the copays, Biotek assured patients that they would not have to pay anything out of pocket. When employees emailed Sparkler about patients who complained about invoices, Sparkler ordered the employees to waive the copays, even for patients who could pay. For example, in a March 2019 email to Sparkler, Tabby reported that patient M.S. "[w]ants no more home infusion for cost reasons" and is "freaking" about her bill. Sparkler responded, "We will work it out with her!!" In another email exchange in 2020, Sparkler wrote: "Please keep in mind – we never want to lose a patient over money! There is a place where even if they don't qualify I can sign off. But we have to have the paperwork. Last resort is that I will sign off if they give pushback to payment plan."

III. The Biotek Defendants' Kickbacks to Tabby

69. In addition to the routine waiver of his patients' copays, the Biotek Defendants provided numerous other kickbacks to Tabby during the relevant time period.

70. This scheme began in August 2015, when Sparkler emailed Tabby to inform him that she had resigned from her prior position to join Biotek. She stated: "As I know you are aware Non Competes come into play HOWEVER I still want to do business with you and I hope you will still do business with me." Tabby replied: "[M]y allegiance is to you."

71. True to his word, Tabby followed Sparkler to Biotek, eventually becoming Biotek's top referring physician. In exchange, the Biotek Defendants rolled out the red carpet for Tabby, providing him with numerous meals, gifts, and other free services that saved Tabby time and helped him make money, to induce Tabby to provide a stream of patient referrals to Biotek.

72. In fact, during the relevant time period, Tabby referred 37% of his Part D business to Biotek. The scheme orchestrated between the Biotek Defendants and Tabby is reflected in a January 2016 email exchange between Sparkler and Tabby, in which Sparkler states: "Thanks to your help I hit my first quarter goals. . . . I can't thank you enough, ever!!! As a result. . . I got that bump in pay so no more salary cut. . . . Life is good." Tabby replied: "Here's to a beautiful relationship."

A. Meals, Tickets, Gifts, and Other Remuneration

73. The Biotek Defendants provided Tabby, as well as members of his family and staff, with food and drinks throughout the relevant time period. For example, just a few days after leaving her prior employer, on August 29, 2015, Sparkler offered to take Tabby, his wife, and his staff to dinner on Biotek's dime. The dinner, which occurred on October 5, 2015, was attended by Sparkler, Gadde, Tabby, and Tabby's wife. Tabby emailed Gadde the next day, copying Sparkler, to inform them that he had "had a great time" and "look[ed] forward to a beautiful relationship." He concluded the email by stating: "Your generosity is gigantic." Gadde responded that he looked forward to hosting Tabby at Gadde's golf club in the future.

74. Following this initial dinner, the Biotek Defendants continued to wine and dine Tabby, and sometimes his family members, and office staff. For example:

a. August 2016: Gadde and Sparkler treated Tabby and three of Tabby's guests to dinner.

b. March 2017: Gadde and Sparkler treated Tabby, his wife, and his office staff to a dinner at Del Frisco's Double Eagle Steak House in Philadelphia.

c. November 2017: Gadde and Sparkler treated Tabby and his wife to dinner at a Chinese restaurant in Philadelphia picked by Tabby's wife.

d. December 2017: Biotek, through Sparkler, paid $230 for a holiday party for Tabby and his staff at a local brewery.

e. December 2017: The same day as the holiday party, Sparkler had Biotek pay $64 for a lunch held at Tabby's office.

f. January 2018: Biotek paid $60 for pizza and pastries for Tabby's office.

g. June 2018: Gadde and Sparkler treated Tabby and his wife, daughter, and members of his staff to dinner.

75. The kickbacks to Tabby were not limited to meals, however. For example, in March 2019, Biotek paid over $4,000 for a suite for Tabby – and, at Tabby's request his wife and a couple members of his staff – to attend a professional basketball game in Philadelphia. Biotek also paid for members of another neurology practice to attend that game in the suite and requested that Tabby use his influence to persuade those physicians to refer business to Biotek. Specifically, a Biotek employee emailed Tabby before the game, stating: "I could really use your help by being there because [another neurology practice] will be there . . . and I figured having you there with your experience working with us could really help with that." Tabby responded: "understood." After the game, the Biotek employee noted that the game was a "big success," and that it was "great to have Dr. Tabby there" because of Tabby's connections to the other neurology practice. The employee also noted that by the next day, the other neurology practice had already referred a patient to Biotek.

76. The Biotek Defendants provided other remuneration to Tabby, including:

a. November 2016: Sparkler arranged for Biotek to pay for a car to drive Tabby and his wife to Biotek's holiday party, at Tabby's request.

b. December 2017: Sparkler arranged for Biotek to provide for a car service to drive Tabby and his wife to Biotek's holiday party.

c. December 2017: Sparkler billed Biotek for a poster that cost over $100 that she provided to Tabby as a holiday gift.

d. December 2018: Sparkler arranged for Biotek to pay for a limousine to drive Tabby and members of his staff to a holiday party at Sparkler's house.

e. August – December 2019: Sparkler, noting that Tabby was "one of our largest referral sources," had Biotek assist Tabby concerning his father's Medicare benefits and copays so that his father could receive free IVIG services from Biotek.

f. December 2019: Sparkler arranged for Biotek to pay for a meal for 50 people at a shiva for Tabby's father.

B. Free Practice Management and Clinical Support Services

77. In addition to meals and gifts, the Biotek Defendants, and Sparkler in particular, provided other remuneration to Tabby, including free practice management services to assist Tabby in generating additional income through his neurology practice, and free clinical services such as drafting Tabby's clinical notes and letters of medical necessity.

78. Sparkler, who typically visited Tabby's office at least once a week, began to perform practice management services for Tabby in late 2015, when she emailed him: "I'd be happy to be a consultant for you. . . the business woman in me was thinking about how to make

you more money." Tabby then provided Sparkler with access to his financial and billing records so that Sparkler could analyze his records and help him generate more income through his practice. For example:

a. April 2017: Sparkler emailed Tabby's billing company to discuss some issues concerning his accounts. When questioned by the company, Sparkler informed the billing company employee that she is working "in a consultative role for Dr. Tabby and review[s] his Authorizations as well as Accounts Receivable."

b. May 2017: Sparkler analyzed Tabby's claims for reimbursement and suggested ways in which Tabby could change his medical notes to get authorization for denied claims. In an email to Tabby's medical billing company, Sparkler noted that one of Tabby's claims had been denied because the insurance company had rejected Tabby's diagnosis code, and she suggested that the billing company talk to Tabby about "downgrading" the diagnosis code to get the claim approved.

c. May 2017: Sparkler analyzed Tabby's billing records and asked Tabby's billing contractor to increase his fees for certain services so that Tabby wasn't "leaving money on the table."

d. August 2017: Tabby introduced Sparkler to an employee in his billing company and informed them that Sparkler "helps me with financial matters in the practice."

e. December 2017: Sparkler reviewed Tabby's financial records and made suggestions for how he could increase his income in the upcoming year.

f. March 2018: Sparkler informed Tabby that she wanted to "dive deeper into the numbers to understand why" Tabby was "making less this year."

g. May 2018: Sparkler informed Tabby that she would impersonate one of Tabby's office assistants to help renegotiate Tabby's contracts with insurance companies.

h. April 2020: Sparkler made additional suggestions to Tabby for increasing his charges to Medicare.

i. August 2020: Sparkler advised Tabby on how to make more money for himself and Biotek from his office infusion suite.

79. Sparkler and other Biotek employees also provided Tabby with clinical support services, helping to write his clinical notes and letters of medical necessity. In addition, Sparkler impersonated a physician so that she could perform Tabby's "peer-to-peers" – conversations that physicians typically have with insurance companies after a claim has been denied in order to explain the bases for medical orders or prescriptions and get the claim approved – so that Tabby would not have to spend his own time doing so. For example:

a. November 2015: Sparkler informed Gadde that she was helping Tabby to appeal denials of insurance claims for two of Tabby's patients, noting that one of the patients "will be worth 1600-1700 month/profit" to Biotek.

b. February 2016: Sparkler informed Tabby: "I played Doc – and did your peer-to-peer."

c. October 2016: Sparkler informed Tabby that she had talked to a patient's insurance company and that Tabby needed to change a patient's treatment plan to get a claim approved.

d. November 2016: Sparkler asked Tabby to write a prescription for a patient, D.J., so that Biotek could treat the patient in its infusion suite.

e. November 2016: Sparkler emailed Tabby about a patient, S.P., and made numerous suggestions to his clinical notes, stating that the insurance company "will eat me up with it if we don't change a couple of things."

f. February 2017: Sparkler asked Tabby to add specific information to his notes about a certain patient, M.M., so that insurance would approve the claim.

g. March 2017: Sparkler instructed another Biotek employee to schedule a time for Sparkler to perform a peer-to-peer for Tabby after an insurance company denied coverage for one of his patients.

h. March 2017: Sparkler informed Tabby that her letter of medical necessity was successful in getting insurance to approve a patient's claim, to which Tabby replied: "Fan-f-tastic."

i. October 2017: Sparkler informed Tabby that she had completed a peer-to-peer discussion for one of his patients, and that after she "finished speaking with the medical Director they approved the medical necessity."

j. December 2017: Tabby emailed Sparkler, asking: "Uh, can you be Dr tabby?" to perform one of his peer-to-peers, to which Sparkler replied: "Every time Darling. . . I always do them for you."

k. January 2018: Sparkler emailed Tabby and another Biotek employee about a patient, stating: "I will speak to Dr tabby [sic] about Diagnosis and notes that will qualify her."

l. April 2018: Sparkler asked other Biotek employees to schedule a peer-to-peer discussion with an insurance company on Tabby's behalf to understand why the insurance company had denied Tabby's claims.

m. April 2018: Sparkler changed Tabby's patient records, adding medications and altering recommended doses.

n. May 2018: A Biotek employee informed Sparkler that Tabby needed to backdate a prescription for an audit.

o. June 2018: Sparkler copied Gadde on an email to another Biotek employee, and stated: "Gather every denial and figure out exactly what the note from Tabby needs to say."

p. June – July 2018: Sparkler drafted care plans for Tabby's patients.

q. November 2018: Tabby asked Sparkler to perform a peer-to-peer for him, to which she replied "OK, I'll look at the notes and everything and give them a call."

r. November 2018: Sparkler asked Tabby to put incorrect information in his clinical notes about patient M.F. so that insurance would cover Tabby's prescribed treatment.

s. February 2019: Sparkler instructed another Biotek employee to draft a letter of medical necessity for one of Tabby's patients, R.M.

t. September 2019: Tabby asked another Biotek employee to have Sparkler do a peer-to-peer for him, stating: "Can Dr. Carla do the peer-to-peer?"

u. September 2019: Sparkler emailed Tabby's assistant a letter of medical necessity for patient T.F.

v. October 2019: Sparkler instructed another Biotek employee to write a letter of medical necessity for one of Tabby's patients.

w. October 2019: Sparkler informed Tabby that she had tried to write Tabby's notes for patient, M.B.

x. October 2019: Sparkler informed Tabby about a certain patient, L.R., stating: "I put everything I could in his cahrt [sic] for you based on his new patient registration. I just need you to add the EMG like you do."

y. February 2020: Sparkler informed Tabby that she had to make some changes to his medical notes.

80. Tabby solicited and accepted these kickbacks and in return referred numerous patients to Biotek. From at least August 2015 through at least May 2020, the patients referred by Tabby accounted for over $20 million in Part D revenues to Biotek.

IV. Kickbacks to Other Doctors

81. In addition to Tabby, the Biotek Defendants provided kickbacks, including meals, gifts, and limousine service to Biotek's holiday parties, to other physicians. The expense reports of Sparkler and other Biotek employees show the following gifts to physicians who referred business to Biotek:

a. March 2016: Sparkler invited Dr. J.S. for dinner at an exclusive Delaware restaurant, Krazy Kats, and noted in the invitation, which she also sent to Gadde, that J.S. should: "please invite whomever [he] would like."

b. May 2016: Biotek provided hospital employees with tickets to Tin Angel, a Philadelphia concert venue.

c. June 2016: Gadde and Sparkler entertained Dr. J.S. at the Fieldstone Golf Club in Delaware. Sparkler emailed Dr. J.S., stating: "It's about that time again. Time to go have some have fun!" To which Gadde replied "Awesome!!!"

d. June 2016: Sparkler invited Dr. J.S. for dinner at Harry Seafood in Wilmington, Delaware. Sparkler also sent the invitation to Gadde and encouraged J.S. to bring his staff and another doctor who referred patients to Biotek.

e. October 2017: Biotek paid a $700 tab for a going away party for a manager at a physician's office, during which Sparkler encouraged the practice to "Order what you need please."

f. April 2018: Biotek gave Pink concert tickets that cost over $400 to a hospital group.

g. May 2018: Biotek gave a $150 gift card to another practice in honor of Nurse's Week.

h. May 2018: Biotek gave a home health practice over $200 in tickets to a ball game.

i. May 2018: Biotek gave a $125 gift certificate to a physician's office and listed the gift on its expense report as "sales and marketing."

82. Sparkler and other Biotek employees also provided free administrative services for Biotek's referring doctors. For example:

a. April 2017: Sparkler performed a peer-to-peer for a physician and had the physician's staff falsely inform the insurance company that Sparkler was a physician's assistant.

b. October 2017: Sparkler told her staff that she handled a peer-to-peer review for Dr. J.S.

c. October 2017: Sparkler explained to a medical professional that Biotek was "here to take some of the pressure/work away from all the things you're already doing" by handling administrative tasks like peer-to-peer reviews.

d. November 2017: Biotek employees informed Sparkler that they scheduled her to conduct a peer-to-peer review for a regular referral source for Biotek, Dr. E.A.

e. January 2019: Sparkler and Biotek employees created a letter of medical necessity for Dr. J.S. for the physician's staff to sign.

f. August 2020: Sparkler explained to Dr. A.L. how she appealed a patient's insurance denial herself.

THE DEFENDANTS KNOWINGLY AND WILLFULLY VIOLATED THE AKS

83. During the relevant time period, the Defendants knowingly and willfully created and participated in the kickback schemes as described herein.

84. At all times relevant to this Complaint and as described herein, the Biotek Defendants knowingly and willfully routinely waived the copays of patients without regard for financial need and knew that at least one purpose of providing this remuneration was to induce patients to purchase drugs from Biotek.

85. At all times relevant to this Complaint and as described herein, the Biotek Defendants knowingly and willfully provided remuneration to Tabby and other physicians and knew that at least one purpose of this remuneration was to induce those physicians to refer patients to Biotek.

86. At all times relevant to this Complaint and as described herein, Tabby solicited and received remuneration from the Biotek Defendants and knew that at least one reason that he referred patients to Biotek was because of the remuneration that he solicited and received.

THE DEFENDANTS SUBMITTED OR CAUSED THE SUBMISSION OF MATERIALLY FALSE CLAIMS TO MEDICARE

87. As a result of the foregoing conduct, the Defendants submitted, or caused the submission of, thousands of false claims to Medicare Part D for prescription drugs.

I. MEDICARE PAYMENTS FOR PRESCRIPTION DRUGS UNDER MEDICARE PART D

88. Generally, after a physician writes a prescription for a Medicare Part D beneficiary, that patient can take the prescription to a pharmacy (or submit it to a mail order specialty pharmacy) to be filled.

89. When the patient submits the prescription, the copay is due from the patient to complete the purchase of the drug and have the pharmacy fill the prescription by dispensing it to the Part D beneficiary.

90. When the pharmacy dispenses drugs to the beneficiary, the pharmacy submits a claim to the beneficiary's Plan Sponsor, which, in turn, submits an electronic record of the claim, called a Prescription Drug Event ("PDE"), to CMS. After dispensing the drug, the pharmacy receives reimbursement from the CMS-funded Plan Sponsor for the portion of the drug cost not paid by the beneficiary at the point of sale.

91. The PDE contains many specific representations regarding this Medicare prescription drug claim, including the patient's name, service provider of the drug, the prescriber of the drug, the name of the drug, and the quantity dispensed to the patient. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as a request for payment for each individual prescription submitted to Medicare under the Part D program.

92. Generating and submitting PDE claims data is necessary for CMS to administer the Part D program and to reimburse Plan Sponsors for qualified drug coverage that they provide to Medicare beneficiaries. Generating and submitting PDE data is a condition of payment for CMS's provision of Medicare funds to Plan Sponsors. *See* 42 C.F.R. § 423.322.

93. CMS pays Plan Sponsors based on PDEs in various ways. For example, CMS provides each Plan Sponsor with advance monthly payments to cover, among other things, the Plan Sponsor's direct CMS subsidy per enrollee (which is based on a standardized bid made by the Plan Sponsor) and estimated reinsurance subsidies (to account for CMS's anticipated 80 percent subsidy of "catastrophic coverage" costs that will be incurred for all enrollees). *See id*. §§ 423.315, 423.329. At the end of the payment year, CMS then reconciles the advance payments paid to each Plan Sponsor with the actual costs that the sponsor has incurred, as documented by PDE data. In this reconciliation process, CMS uses the PDE claims data submitted by the Plan Sponsor during the prior payment year to calculate the costs that the Plan Sponsor has actually incurred for prescriptions filled by Medicare beneficiaries under Part D that year.[3] The payments made by CMS to the Plan Sponsor – which in turn fund the provision of

[3] CMS also uses PDE data to determine risk-sharing amounts owed by CMS to the plan or (if a plan significantly overestimated its non-catastrophic costs in its bid) owed by the plan to CMS.

prescription drugs provided to beneficiaries at each drug-dispensing event – come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. § 423.315(a).

94. Plan Sponsors must comply with "[f]ederal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. §§ 3729 et seq.), and the anti-kickback statute (§ 1127B(b)) of the Act)." 42 C.F.R. § 423.505(i)(3)(iv).

95. CMS regulations require Plan Sponsors and related "downstream" entities that generate and submit PDE claims data to certify that such data is true, accurate, and complete and that the PDE data is the basis for obtaining federal reimbursement for the health care products or services reflected therein. *Id.* at § 423.505(k).

II. PHYSICIAN CERTIFICATIONS UNDER THE MEDICARE PROGRAM

96. To participate in the Medicare program as a new enrollee, a physician must submit a Medicare Enrollment Application, Form CMS-855I. A provider also must complete Form CMS-855I to change information or to reactivate, revalidate, and/or terminate Medicare enrollment.

97. Form CMS-855I requires, among other things, signatories to certify:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in section 4A of this application. The Medicare laws, regulations, and program instructions are available through the Medicare Administrative Contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions

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These risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages. *See* 42 C.F.R. § 423.336.

> (including, but not limited to, the Federal Anti-Kickback Statute, 42 U.S.C. section 1320a-7b(b) . . . .
>
> * * *
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

See https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855i.pdf (last visited June 28, 2021).

98. The provider must sign the "Certification Section" in Section 15 of Form CMS-855I, and in doing so, is "attesting to meeting and maintaining the Medicare requirements" excerpted above, among others. *Id*.

III. THE DEFENDANTS' VIOLATIONS WERE MATERIAL TO THE PAYMENT DECISION

99. Compliance with the AKS is a material condition of payment by Medicare. The centrality of the AKS to the claims payment decision is demonstrated by the fact that Congress has determined that any Medicare claim "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g).

100. Persons and entities submitting claims to Medicare are subject to mandatory exclusion from Medicare by HHS-OIG if criminally convicted of an AKS violation, 42 U.S.C. § 1320a-7(a)(1), and are subject to permissive exclusion if HHS-OIG determines that the provider "has committed an act" described in the AKS, 42 U.S.C. § 1320a-7(b)(7).

101. HHS-OIG has made clear that compliance with the AKS is material. It has also specifically provided guidance on its views of the risks inherent in companies waiving copay subsidies, stating that routine waivers of copayments can trigger an AKS violation.

102. CMS has also made clear to physicians on Form CMS-855I that compliance with the AKS is a condition of payment under Medicare.

103. The United States regularly enforces the AKS and pursues FCA liability based on underlying violations of the AKS. In particular, it has pursued entities for conduct like that alleged here.

104. The conduct by the Defendants undermined the core concerns of the AKS – in particular – preventing excessive costs to Medicare resulting from illegal copay subsidies that facilitate high costs and push the financial burden of those costs to Medicare.

105. The Defendants' conduct was sustained and systemic. It lasted over multiple years and involved thousands of claims submitted to Medicare. The kickbacks at issue here were for millions of dollars in total and were not insignificant.

106. Compliance with the regulatory requirement that the PDE data submitted to CMS is "true, accurate, and complete" is an express condition of payment under the Medicare Part D Program.

107. The submission of PDEs is essential to the functioning of the Part D Program, the singular purpose of which is to provide coverage for drug products for the Medicare population. The accuracy of the information contained in each PDE for each patient determines how much payment will be made by Part D for that particular prescription.

108. The scheme alleged here resulted in thousands of PDEs being submitted to Part D over a period of multiple years.

SAMPLE FALSE CLAIMS

109. Through the schemes described above, the Biotek Defendants provided illegal copay waivers for hundreds of prescriptions to induce patients to purchase drugs from Biotek and

to use Biotek's services, resulting in millions of dollars of false claims to Medicare during the relevant time period.

110. Throughout the relevant time period, Biotek's patients were induced by these copay waivers to purchase drugs from Biotek. Biotek submitted claims for these drugs to Medicare Part D Sponsors to receive reimbursement for those prescriptions. These false claims are documented in the PDE data. Moreover, Plan Sponsors, in turn, submitted these false PDE data to CMS as the basis for payments from the federal government based upon the expenses incurred for these illegally waived prescriptions.

111. PDE data attached as Exhibit 1 demonstrates representative examples of false claims for the prescriptions of ten Medicare patients (two of whom are Dr. Tabby patients) with copays above $2,500 who were the subject of the Biotek Defendants' illegal copay waivers and reimbursed by Medicare. Each line item on this exhibit represents a distinct PDE reflecting a false Medicare claim. In each instance, the drug is identified by both its "National Drug Code" ("NDC Code") and its common name ("NDC Code Description") from the PDE data. In each line item, the PDE data also shows the Medicare Part D beneficiary who received the drug, reported here in the "Beneficiary" field, and the physician who referred the patient, reported here in the "Prescriber" field (using a de-identified value for purposes of this exhibit). The amount of the copay that was waived for each claim is listed as "Amt Pd Bene POS."

112. The Biotek Defendants also provided illegal kickbacks to Tabby that resulted in millions of dollars of false claims to Medicare during the relevant time period.

113. Throughout the relevant time period, the Biotek Defendants paid kickbacks to Tabby to induce Tabby to refer numerous patients to Biotek. Biotek submitted claims for drugs purchased by these referred patients to Medicare Part D Sponsors to receive reimbursement for

these prescriptions. Plan Sponsors, in turn, submitted these false PDE data to CMS as the basis for payments from the federal government based upon these expenses incurred for these prescriptions.

114. PDE data attached as Exhibit 2 demonstrates examples of false claims for prescriptions that were purchased by the patients referred by Tabby to Biotek. Each line item on this exhibit represents a distinct PDE reflecting a false Medicare claim. As in Exhibit 1, in each instance, the drug is identified by both its "National Drug Code" ("NDC Code") and its common name ("NDC Code Description") from the PDE data. In each line item, the PDE data also shows the Medicare Part D beneficiary who received the drug, reported here in the "Beneficiary" field (using a de-identified value for purposes of this exhibit).

THE CLAIMS ARE FALSE CLAIMS

115. The Biotek Defendants knowingly submitted, or caused the submission of, false claims for reimbursement to Medicare when it routinely waived, without regard to financial need, the copays of the 237 Medicare patients discussed herein.

116. The Biotek Defendants and Tabby knowingly submitted, or caused the submission of, false claims for reimbursement to Medicare for the claims submitted for patients referred to Biotek by Tabby.

117. The claims are per se false and fraudulent as a matter of law. 42 U.S.C. §1320a-7b(g).

118. The claims are also false because the PDE data and the specific representations therein fail to disclose a violation of a requirement material to the agency's payment decision, namely the AKS.

119. The PDE data was not true, accurate, and complete because it did not disclose a violation of the AKS. The PDE data for each claim was a false record that the Defendants caused to be used to pay the false claims alleged herein.

120. The representations of compliance with the AKS made by the Part D Plan Sponsor and downstream entities were false because the claims resulted from an illegal kickback. The representations were false records that the Defendants caused to be used to pay the false claims.

COUNT I
(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1)(A))

121. The United States re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

122. By virtue of the acts described above, the Defendants knowingly presented or caused to be presented materially false or fraudulent claims for payment or approval to Medicare in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A); that is, the Defendants knowingly made or presented, or caused to be made or presented, to the United States claims for payment for prescription drugs that were tainted by illegal kickbacks.

123. Payment of the false and fraudulent claims was a reasonable and foreseeable consequence of the Defendants' conduct.

124. By reason of the foregoing, the United States has been damaged in an amount to be determined at trial and is entitled to recover treble damages plus a civil monetary penalty for each false and fraudulent claim.

COUNT II
(False Claims Act: False Records Material To a False or Fraudulent Claim)
(31 U.S.C. § 3729(A)(1)(B))

125. The United States re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

126. By virtue of the acts described above, the Defendants knowingly made, used, or caused to be made or used, false records or statements, namely, false claims, false statements in PDEs, and false statements about compliance with the AKS, all of which were material to false or fraudulent claims that were submitted to the United States and paid and approved by the Medicare program for prescription drugs that were tainted by illegal kickbacks, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

127. Payment of the false and fraudulent claims was a reasonable and foreseeable consequence of the Defendants' conduct.

128. By reason of the false or fraudulent records or statements, the United States has been damaged in an amount to be determined at trial and is entitled to recover treble damages plus a civil monetary penalty for each false record or statement.

COUNT III
(Unjust Enrichment)

129. The United States re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

130. By virtue of the acts described above, the United States paid claims submitted to Medicare for prescription drugs that were tainted by kickbacks. The Defendants' receipt of payments based on their kickback schemes are such that, in equity and good conscience, the Defendants should not retain those payments.

131. By reason of the Defendants' acts, the United States has been damaged in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, plaintiff, the United States, requests that judgment be entered in its favor as follows:

I. On Count I under the False Claims Act against the Defendants, for the amount of the United States' damages to be established at trial, trebled as required by law, and such civil penalties as are authorized by law, and all such further relief the Court deems just and proper.

II. On Count II under the False Claims Act against the Defendants, for the amount of the United States' damages to be established at trial, trebled as required by law, and such civil penalties as are authorized by law, and all such further relief the Court deems just and proper.

III. On Count III under the common law against the Defendants, for the amount of the United States' damages to be established at trial, and all such further relief the Court deems just and proper.

IV. All other and further relief as the Court deems just and proper.

The United States hereby demands a jury trial on all claims alleged herein.

Respectfully submitted,

BRIAN M. BOYNTON
Acting Assistant Attorney General

JAMIE A. YAVELBERG
Director
Commercial Litigation Branch

NATALIE WAITES
Assistant Director
Commercial Litigation Branch

/s/Jennifer L. Cihon
JENNIFER L. CIHON
ELSBETH J. BENNETT
Attorneys, Civil Division
United States Department of Justice
P.O. Box 261, Ben Franklin Station
Washington, DC 20044
Phone: (202) 514-7371

JENNIFER ARBITTIER WILLIAMS
Acting United States Attorney

/s/Gregory B. David
GREGORY B. DAVID
Assistant United States Attorney
Chief, Civil Division

/s/Charlene Keller Fullmer
CHARLENE KELLER FULLMER
Assistant United States Attorney
Deputy Chief, Civil Division

/s/Jacqueline C. Romero
JACQUELINE C. ROMERO
JUDITH AMOROSA
Assistant United States Attorneys
United States Attorney's Office
615 Chestnut Street, Suite 1250
Philadelphia, PA 19106
(215) 861-8470 (Romero)
(215) 861-8869 (Amorosa)

Attorneys for the United States

Dated: July 6, 2021

Exhibit 1

Final for Exhibit I

	A	B	C	D	E	F	G	H	I	J	K	L
1	Sample False Claim No.	NDC Code	NDC Code Description	Units Quan Disp	Amt Above OOPT	Amt Below OOPT	Amt Pd Bene POS	Beneficiary	Date From Hdr	Date Processed	Pharm Name	Prescriber
2	1	00069131202	PANZYGA	2,000	26,964.38	9,262.63	3,944.61	L, N	01/09/2020	01/14/2020	Biotek Remedys	MD-02
3	2	68982085003	OCTAGAM	2,000	23,260.24	9,307.80	3,811.55	B, M	01/16/2020	03/17/2020	Biotek Remedys	MD-04
4	3	13533080020	GAMUNEX-C	1,400	7,296.70	7,345.65	3,567.00	C, D	01/11/2018	01/17/2018	Biotek Remedys	MD-01
5	4	68982084004	OCTAGAM	4,000	23,454.14	7,861.48	3,443.66	K, A	03/13/2019	06/04/2019	Biotek Remedys	MD-02
6	5	44206043940	PRIVIGEN	1,600	14,685.52	9,307.80	3,382.81	K, A	01/16/2020	01/21/2020	Biotek Remedys	MD-02
7	6	68982084004	OCTAGAM	4,000	20,300.38	6,940.83	3,365.86	N, J	08/01/2017	08/16/2017	Biotek Remedys	MD-01
8	7	44206043710	PRIVIGEN	1,500	11,739.85	8,150.15	3,354.05	K, J	01/19/2018	06/06/2018	Biotek Remedys	MD-02
9	8	68982085004	OCTAGAM	2,000	16,009.30	7,861.48	3,071.42	L, N	01/03/2019	02/19/2019	Biotek Remedys	MD-02
10	9	68982085003	OCTAGAM	1,500	15,709.04	7,777.93	3,031.35	B, M	01/29/2019	02/26/2019	Biotek Remedys	MD-04
11	10	13533080020	GAMUNEX-C	1,400	8,137.49	7,389.58	3,008.16	C, D	01/07/2019	01/16/2019	Biotek Remedys	MD-01
12	11	68982084004	OCTAGAM	4,000	16,881.43	6,055.60	2,928.18	L, N	05/18/2018	05/22/2018	Biotek Remedys	MD-02
13	12	44206043710	PRIVIGEN	1,500	12,724.12	7,855.53	2,911.34	K, J	01/02/2019	01/30/2019	Biotek Remedys	MD-02
14	13	44206043710	PRIVIGEN	1,500	11,962.41	8,933.54	2,880.75	K, J	01/23/2020	01/29/2020	Biotek Remedys	MD-02
15	14	00944270003	GAMMAGARD LIQUID	975	3,956.42	9,302.89	2,849.80	N, J	01/10/2020	01/15/2020	Biotek Remedys	MD-01
16	15	13533080012	GAMUNEX-C	800	1,371.87	7,691.02	2,693.73	C, M	01/29/2018	02/09/2018	Biotek Remedys	MD-03
17	16	44206043710	PRIVIGEN	600	1,533.97	7,378.95	2,685.43	R, L	01/04/2019	01/08/2019	Biotek Remedys	MD-06
18	17	44206043605	PRIVIGEN	650	501.33	9,241.51	2,653.93	R, L	01/13/2020	01/20/2020	Biotek Remedys	MD-06
19	18	13533080020	GAMUNEX-C	2,250	17,549.64	6,000.30	2,377.55	P, R	04/30/2019	05/06/2019	Biotek Remedys	MD-03
20	19	44206043940	PRIVIGEN	400	0.00	5,829.85	2,322.27	R, L	01/31/2018	02/07/2018	Biotek Remedys	MD-06
21	20	68982085003	OCTAGAM	2,000	36,475.24	0.00	1,823.76	B, M	02/18/2020	03/17/2020	Biotek Remedys	MD-04
22	21	68982085003	OCTAGAM	2,000	36,475.24	0.00	1,823.76	B, M	03/17/2020	03/24/2020	Biotek Remedys	MD-04
23	22	68982085003	OCTAGAM	2,000	36,475.24	0.00	1,823.76	B, M	04/14/2020	04/21/2020	Biotek Remedys	MD-04
24	23	68982085003	OCTAGAM	2,000	36,475.24	0.00	1,823.76	B, M	05/13/2020	05/19/2020	Biotek Remedys	MD-04
25	24	00069131202	PANZYGA	2,000	36,227.01	0.00	1,811.35	L, N	02/06/2020	02/11/2020	Biotek Remedys	MD-02
26	25	00069131202	PANZYGA	2,000	36,227.01	0.00	1,811.35	L, N	02/28/2020	03/03/2020	Biotek Remedys	MD-02
27	26	00069141502	PANZYGA	2,000	36,227.01	0.00	1,811.35	L, N	03/16/2020	03/25/2020	Biotek Remedys	MD-02
28	27	00069131202	PANZYGA	2,000	36,227.01	0.00	1,811.35	L, N	04/27/2020	05/05/2020	Biotek Remedys	MD-02
29	28	13533080020	GAMUNEX-C	550	0.00	5,900.60	1,801.40	P, R	01/02/2020	01/21/2020	Biotek Remedys	MD-03
30	29	68982082005	PANZYGA	2,000	35,470.05	0.00	1,773.50	L, N	06/20/2019	06/25/2019	Biotek Remedys	MD-02
31	30	68982082004	PANZYGA	2,000	35,470.05	0.00	1,773.50	L, N	07/11/2019	07/16/2019	Biotek Remedys	MD-02
32	31	68982082004	PANZYGA	2,000	35,470.05	0.00	1,773.50	L, N	08/01/2019	08/06/2019	Biotek Remedys	MD-02
33	32	68982082004	PANZYGA	2,000	35,470.05	0.00	1,773.50	L, N	08/22/2019	08/27/2019	Biotek Remedys	MD-02
34	33	68982082004	PANZYGA	2,000	35,470.05	0.00	1,773.50	L, N	09/11/2019	09/17/2019	Biotek Remedys	MD-02
35	34	00069131202	PANZYGA	2,000	35,470.05	0.00	1,773.50	L, N	10/22/2019	10/29/2019	Biotek Remedys	MD-02
36	35	00069131202	PANZYGA	2,000	35,470.05	0.00	1,773.50	L, N	11/12/2019	11/19/2019	Biotek Remedys	MD-02
37	36	00069131202	PANZYGA	2,000	35,470.05	0.00	1,773.50	L, N	12/05/2019	12/10/2019	Biotek Remedys	MD-02
38	37	00069131202	PANZYGA	2,000	35,470.05	0.00	1,773.50	L, N	12/23/2019	12/31/2019	Biotek Remedys	MD-02
39	38	44206043820	PRIVIGEN	400	0.00	5,304.25	1,754.06	N, J	01/15/2018	07/18/2018	Biotek Remedys	MD-01
40	39	00944270005	GAMMAGARD LIQUID	400	0.00	5,366.03	1,641.45	N, J	01/07/2019	01/16/2019	Biotek Remedys	MD-01
41	40	68982085003	OCTAGAM	2,000	32,568.04	0.00	1,628.40	B, M	09/20/2019	09/24/2019	Biotek Remedys	MD-04
42	41	68982085003	OCTAGAM	2,000	32,568.04	0.00	1,628.40	B, M	10/25/2019	10/29/2019	Biotek Remedys	MD-04
43	42	68982085003	OCTAGAM	2,000	32,568.04	0.00	1,628.40	B, M	11/25/2019	12/03/2019	Biotek Remedys	MD-04
44	43	68982085003	OCTAGAM	2,000	32,568.04	0.00	1,628.40	B, M	12/23/2019	01/02/2020	Biotek Remedys	MD-04
45	44	68982084004	OCTAGAM	4,000	32,568.04	0.00	1,628.40	K, A	05/17/2019	06/04/2019	Biotek Remedys	MD-02
46	45	68982084004	OCTAGAM	4,000	31,315.62	0.00	1,565.78	K, A	04/11/2019	06/04/2019	Biotek Remedys	MD-02
47	46	51224042510	TETRABENAZINE	90	0.00	4,082.52	1,510.53	G, T	03/11/2019	03/27/2019	Biotek Remedys	MD-05
48	47	44206043710	PRIVIGEN	2,000	29,991.40	0.00	1,499.57	K, A	08/09/2019	08/20/2019	Biotek Remedys	MD-02
49	48	44206043710	PRIVIGEN	2,000	29,991.40	0.00	1,499.57	K, A	09/12/2019	09/17/2019	Biotek Remedys	MD-02
50	49	44206043710	PRIVIGEN	2,000	29,991.40	0.00	1,499.57	K, A	10/08/2019	10/15/2019	Biotek Remedys	MD-02
51	50	44206043940	PRIVIGEN	2,000	29,991.40	0.00	1,499.57	K, A	11/01/2019	11/05/2019	Biotek Remedys	MD-02
52	51	44206043940	PRIVIGEN	2,000	29,991.40	0.00	1,499.57	K, A	11/22/2019	11/26/2019	Biotek Remedys	MD-02
53	52	51224042510	TETRABENAZINE	90	58.11	4,024.41	1,492.43	G, T	04/15/2019	04/24/2019	Biotek Remedys	MD-05
54	53	44206043710	PRIVIGEN	2,000	29,357.80	0.00	1,467.89	K, A	06/20/2019	07/02/2019	Biotek Remedys	MD-02
55	54	44206043710	PRIVIGEN	2,000	29,357.80	0.00	1,467.89	K, A	07/19/2019	07/30/2019	Biotek Remedys	MD-02
56	55	13533080020	GAMUNEX-C	400	0.00	4,585.42	1,451.95	C, M	01/09/2019	01/15/2019	Biotek Remedys	MD-03
57	56	51224042510	TETRABENAZINE	90	0.00	4,082.52	1,408.84	G, T	02/05/2019	02/13/2019	Biotek Remedys	MD-05
58	57	13533080071	GAMUNEX-C	1,100	8,400.60	3,400.79	1,270.23	P, R	01/22/2020	02/04/2020	Biotek Remedys	MD-03
59	58	68982085004	OCTAGAM	2,000	24,825.60	0.00	1,241.28	L, N	05/07/2019	05/15/2019	Biotek Remedys	MD-02
60	59	68982085004	OCTAGAM	2,000	24,825.60	0.00	1,241.28	L, N	05/30/2019	06/05/2019	Biotek Remedys	MD-02
61	60	68982085003	OCTAGAM	1,500	24,426.28	0.00	1,221.31	B, M	06/04/2019	06/11/2019	Biotek Remedys	MD-04
62	61	68982085003	OCTAGAM	1,500	24,426.28	0.00	1,221.31	B, M	06/25/2019	07/02/2019	Biotek Remedys	MD-04
63	62	68982085003	OCTAGAM	1,500	24,426.28	0.00	1,221.31	B, M	07/19/2019	07/23/2019	Biotek Remedys	MD-04
64	63	68982085003	OCTAGAM	1,500	24,426.28	0.00	1,221.31	B, M	08/23/2019	08/27/2019	Biotek Remedys	MD-04
65	64	44206043820	PRIVIGEN	1,600	23,993.32	0.00	1,199.66	K, A	02/26/2020	03/03/2020	Biotek Remedys	MD-02
66	65	44206043820	PRIVIGEN	1,600	23,993.32	0.00	1,199.66	K, A	03/19/2020	03/24/2020	Biotek Remedys	MD-02
67	66	44206043820	PRIVIGEN	1,600	23,993.32	0.00	1,199.66	K, A	04/15/2020	04/21/2020	Biotek Remedys	MD-02
68	67	44206043820	PRIVIGEN	1,600	23,993.32	0.00	1,199.66	K, A	05/15/2020	05/19/2020	Biotek Remedys	MD-02

	A	B	C	D	E	F	G	H	I	J	K	L
1	Sample False Claim No.	NDC Code	NDC Code Description	Units Quan Disp	Amt Above OOPT	Amt Below OOPT	Amt Pd Bene POS	Beneficiary	Date From Hdr	Date Processed	Pharm Name	Prescriber
69	68	51224042510	TETRABENAZINE	60	0.00	2,721.46	1,197.44	G, T	01/31/2018	02/28/2018	Biotek Remedys	MD-05
70	69	51224042510	TETRABENAZINE	60	0.00	2,721.46	1,197.44	G, T	02/26/2018	03/14/2018	Biotek Remedys	MD-05
71	70	68982085001	OCTAGAM	2,000	23,870.92	0.00	1,193.54	L, N	03/04/2019	03/12/2019	Biotek Remedys	MD-02
72	71	68982085004	OCTAGAM	2,000	23,870.78	0.00	1,193.53	L, N	01/23/2019	02/19/2019	Biotek Remedys	MD-02
73	72	68982085004	OCTAGAM	2,000	23,870.78	0.00	1,193.53	L, N	02/13/2019	02/19/2019	Biotek Remedys	MD-02
74	73	68982085003	OCTAGAM	2,000	23,870.78	0.00	1,193.53	L, N	04/17/2019	04/23/2019	Biotek Remedys	MD-02
75	74	68982085003	OCTAGAM	1,500	23,486.97	0.00	1,174.34	B, M	02/27/2019	03/05/2019	Biotek Remedys	MD-04
76	75	68982085003	OCTAGAM	1,500	23,486.97	0.00	1,174.34	B, M	03/22/2019	03/26/2019	Biotek Remedys	MD-04
77	76	68982084004	OCTAGAM	3,000	23,486.97	0.00	1,174.34	B, M	04/29/2019	05/07/2019	Biotek Remedys	MD-04
78	77	44206043605	PRIVIGEN	850	10,726.76	1,661.29	1,152.28	R, L	03/02/2018	03/07/2018	Biotek Remedys	MD-06
79	78	68982085004	OCTAGAM	2,000	22,953.13	0.00	1,147.65	L, N	11/01/2018	11/06/2018	Biotek Remedys	MD-02
80	79	68982085003	OCTAGAM	2,000	22,953.13	0.00	1,147.65	L, N	11/16/2018	11/20/2018	Biotek Remedys	MD-02
81	80	68982085003	OCTAGAM	2,000	22,953.13	0.00	1,147.65	L, N	12/12/2018	12/18/2018	Biotek Remedys	MD-02
82	81	68982084001	OCTAGAM	4,000	22,952.59	0.00	1,147.62	L, N	09/19/2018	09/28/2018	Biotek Remedys	MD-02
83	82	68982084004	OCTAGAM	4,000	22,937.03	0.00	1,146.85	L, N	06/05/2018	06/13/2018	Biotek Remedys	MD-02
84	83	68982084004	OCTAGAM	4,000	22,937.03	0.00	1,146.85	L, N	06/29/2018	07/03/2018	Biotek Remedys	MD-02
85	84	68982084004	OCTAGAM	4,000	22,937.03	0.00	1,146.85	L, N	08/06/2018	08/14/2018	Biotek Remedys	MD-02
86	85	68982084004	OCTAGAM	4,000	22,937.03	0.00	1,146.85	L, N	10/09/2018	10/16/2018	Biotek Remedys	MD-02
87	86	44206043820	PRIVIGEN	400	2,555.74	2,748.51	1,089.76	N, J	01/30/2018	07/18/2018	Biotek Remedys	MD-01
88	87	00944270006	GAMMAGARD LIQUID	1,600	21,462.03	0.00	1,073.10	N, J	08/13/2019	08/28/2019	Biotek Remedys	MD-01
89	88	44206043710	PRIVIGEN	1,500	21,023.80	0.00	1,051.19	K, J	08/05/2019	08/14/2019	Biotek Remedys	MD-02
90	89	44206043710	PRIVIGEN	1,500	21,023.80	0.00	1,051.19	K, J	09/06/2019	09/11/2019	Biotek Remedys	MD-02
91	90	44206043710	PRIVIGEN	1,500	21,023.80	0.00	1,051.19	K, J	09/27/2019	10/09/2019	Biotek Remedys	MD-02
92	91	44206043710	PRIVIGEN	1,500	21,023.80	0.00	1,051.19	K, J	10/25/2019	11/06/2019	Biotek Remedys	MD-02
93	92	44206043710	PRIVIGEN	1,500	21,023.80	0.00	1,051.19	K, J	11/21/2019	12/04/2019	Biotek Remedys	MD-02
94	93	44206043710	PRIVIGEN	1,500	20,895.95	0.00	1,044.80	K, J	12/19/2019	01/01/2020	Biotek Remedys	MD-02
95	94	44206043710	PRIVIGEN	1,500	20,895.95	0.00	1,044.80	K, J	02/27/2020	03/11/2020	Biotek Remedys	MD-02
96	95	44206043710	PRIVIGEN	1,500	20,895.95	0.00	1,044.80	K, J	03/23/2020	04/09/2020	Biotek Remedys	MD-02
97	96	44206043710	PRIVIGEN	1,500	20,895.95	0.00	1,044.80	K, J	04/20/2020	05/20/2020	Biotek Remedys	MD-02
98	97	44206043710	PRIVIGEN	1,500	20,579.65	0.00	1,028.98	K, J	02/01/2019	02/13/2019	Biotek Remedys	MD-02
99	98	44206043605	PRIVIGEN	1,500	20,579.65	0.00	1,028.98	K, J	02/27/2019	03/13/2019	Biotek Remedys	MD-02
100	99	44206043710	PRIVIGEN	1,500	20,579.65	0.00	1,028.98	K, J	03/28/2019	04/10/2019	Biotek Remedys	MD-02
101	100	44206043710	PRIVIGEN	1,500	20,579.65	0.00	1,028.98	K, J	04/29/2019	05/08/2019	Biotek Remedys	MD-02
102	101	44206043710	PRIVIGEN	1,500	20,579.65	0.00	1,028.98	K, J	05/23/2019	06/05/2019	Biotek Remedys	MD-02
103	102	44206043710	PRIVIGEN	1,500	20,579.65	0.00	1,028.98	K, J	07/02/2019	07/17/2019	Biotek Remedys	MD-02
104	103	51224042510	TETRABENAZINE	90	0.00	4,082.47	1,020.62	G, T	03/16/2020	03/25/2020	Biotek Remedys	MD-05
105	104	51224042510	TETRABENAZINE	90	0.00	4,082.47	1,020.62	G, T	04/09/2020	04/22/2020	Biotek Remedys	MD-05
106	105	51224042510	TETRABENAZINE	90	0.00	4,082.47	1,020.62	G, T	05/08/2020	05/20/2020	Biotek Remedys	MD-05
107	106	44206043710	PRIVIGEN	1,500	20,328.75	0.00	1,016.44	K, J	08/22/2018	08/29/2018	Biotek Remedys	MD-02
108	107	44206043710	PRIVIGEN	1,500	20,328.75	0.00	1,016.44	K, J	09/19/2018	09/26/2018	Biotek Remedys	MD-02
109	108	44206043710	PRIVIGEN	1,500	20,328.75	0.00	1,016.44	K, J	10/17/2018	10/24/2018	Biotek Remedys	MD-02
110	109	44206043710	PRIVIGEN	1,500	20,328.75	0.00	1,016.44	K, J	11/28/2018	12/05/2018	Biotek Remedys	MD-02
111												
112					2,276,438.91	208,341.19	179,345.92					

Exhibit 2

Final Exhibit II

	A	B	C	D	E	F	G	H	I	J	K	L
1	**Sample False Claim No.**	**NDC Code**	**NDC Code Description**	**QTY Dispensed**	**Amt Above OOPT**	**Amt Below OOPT**	**Amt Pd Bene POS**	**Beneficiary**	**Date From Hdr**	**Date Processed**	**Pharm Name**	**Presc IDs**
2	1	50242015001	OCREVUS	20	34,321.00	0.00	1,716.05	T, M	10/23/2019	10/29/2019	Biotek Remedys	MD-01
3	2	50242015001	OCREVUS	20	31,883.15	0.00	1,594.16	T, M	5/13/2020	05/20/2020	Biotek Remedys	MD-01
4	3	68982085003	OCTAGAM	2,000	30,019.34	0.00	0.00	Q, J	4/9/2019	03/06/2020	Biotek Remedys	MD-01
5	4	00944270004	GAMMAGARD LIQUID	2,200	29,706.09	0.00	1,485.30	M, S.2	1/31/2018	02/07/2018	Biotek Remedys	MD-01
6	5	00944270004	GAMMAGARD LIQUID	2,200	29,706.09	0.00	1,485.30	M, S.2	3/5/2018	03/14/2018	Biotek Remedys	MD-01
7	6	50242015001	OCREVUS	20	24,273.08	10,047.92	3,324.17	R, J	4/21/2020	04/28/2020	Biotek Remedys	MD-01
8	7	00944270004	GAMMAGARD LIQUID	1,650	21,959.66	0.00	1,097.98	M, S.2	10/13/2017	10/18/2017	Biotek Remedys	MD-01
9	8	64208823404	GAMMAPLEX	4,000	21,695.77	5,889.40	3,501.15	C, C	3/17/2017	04/17/2018	Biotek Remedys	MD-01
10	9	00944270004	GAMMAGARD LIQUID	2,200	21,529.62	8,176.47	3,863.24	M, S.2	1/5/2018	01/10/2018	Biotek Remedys	MD-01
11	10	68982082004	PANZYGA	1,200	21,287.31	0.00	1,064.37	B, G	7/12/2019	07/16/2019	Biotek Remedys	MD-01
12	11	68982082005	PANZYGA	1,200	21,287.31	0.00	1,064.37	B, G	8/2/2019	08/06/2019	Biotek Remedys	MD-01
13	12	00069131202	PANZYGA	1,500	21,113.08	5,489.58	2,551.92	W, S	10/23/2019	10/29/2019	Biotek Remedys	MD-01
14	13	68982084003	OCTAGAM	2,800	21,078.55	0.00	1,053.92	G, D	7/25/2018	07/31/2018	Biotek Remedys	MD-01
15	14	68982084003	OCTAGAM	2,800	21,078.55	0.00	1,053.92	G, D	8/16/2018	08/21/2018	Biotek Remedys	MD-01
16	15	68982084004	OCTAGAM	4,000	20,546.84	7,677.55	3,846.55	M, S	4/20/2017	04/21/2018	Biotek Remedys	MD-01
17	16	68982084004	OCTAGAM	4,000	19,953.70	7,167.26	3,834.23	H, P	9/2/2016	02/02/2017	Biotek Remedys	MD-01
18	17	13533080071	GAMUNEX-C	1,500	18,214.42	510.91	1,038.44	M, R	7/24/2019	07/29/2019	Biotek Remedys	MD-01
19	18	00944270007	GAMMAGARD LIQUID	1,200	17,776.32	0.00	888.82	B, G	11/6/2019	11/12/2019	Biotek Remedys	MD-01
20	19	00944270007	GAMMAGARD LIQUID	1,200	17,776.32	0.00	888.82	B, G	12/3/2019	12/10/2019	Biotek Remedys	MD-01
21	20	00944270007	GAMMAGARD LIQUID	1,200	17,776.32	0.00	888.82	B, G	12/27/2019	12/30/2019	Biotek Remedys	MD-01
22	21	00944270005	GAMMAGARD LIQUID	1,200	17,557.45	0.00	877.87	B, G	3/12/2020	03/16/2020	Biotek Remedys	MD-01
23	22	00944270005	GAMMAGARD LIQUID	1,200	17,557.45	0.00	877.87	B, G	4/9/2020	04/13/2020	Biotek Remedys	MD-01
24	23	00944270005	GAMMAGARD LIQUID	1,200	17,557.45	0.00	877.87	B, G	5/13/2020	05/19/2020	Biotek Remedys	MD-01
25	24	59730650201	BIVIGAM	1,250	17,557.00	0.00	877.85	T, M	10/8/2019	10/15/2019	Biotek Remedys	MD-01
26	25	00944270005	GAMMAGARD LIQUID	1,200	17,427.53	0.00	871.38	B, G	5/7/2019	05/14/2019	Biotek Remedys	MD-01
27	26	00944270006	GAMMAGARD LIQUID	1,200	17,427.53	0.00	871.38	B, G	6/5/2019	06/11/2019	Biotek Remedys	MD-01
28	27	00944270007	GAMMAGARD LIQUID	1,200	17,427.53	0.00	871.38	B, G	9/16/2019	09/24/2019	Biotek Remedys	MD-01
29	28	00944270007	GAMMAGARD LIQUID	1,200	17,427.53	0.00	871.38	B, G	10/7/2019	10/14/2019	Biotek Remedys	MD-01
30	29	68982084003	OCTAGAM	3,500	16,643.62	7,541.12	3,583.67	G, C	10/17/2017	04/21/2018	Biotek Remedys	MD-01
31	30	68982085002	OCTAGAM	900	16,405.58	0.00	820.28	S, C.2	2/27/2020	03/10/2020	Biotek Remedys	MD-01
32	31	68982085002	OCTAGAM	900	16,405.58	0.00	820.28	S, C.2	3/26/2020	03/30/2020	Biotek Remedys	MD-01
33	32	68982085003	OCTAGAM	900	16,405.58	0.00	820.28	S, C.2	4/17/2020	04/20/2020	Biotek Remedys	MD-01
34	33	68982082003	PANZYGA	900	15,961.80	0.00	798.09	S, C.2	9/30/2019	10/08/2019	Biotek Remedys	MD-01
35	34	00069122402	PANZYGA	900	15,961.80	0.00	798.09	S, C.2	10/31/2019	11/05/2019	Biotek Remedys	MD-01
36	35	68982082003	PANZYGA	900	15,839.39	0.00	791.97	S, C	7/19/2019	03/06/2020	Biotek Remedys	MD-01
37	36	13533080071	GAMUNEX-C	1,500	15,505.78	0.00	775.29	M, L	10/25/2016	11/09/2016	Biotek Remedys	MD-01
38	37	68982085002	OCTAGAM	900	15,501.34	0.00	775.07	S, C	4/14/2020	04/22/2020	Biotek Remedys	MD-01
39	38	68982085002	OCTAGAM	900	15,023.20	478.14	870.69	S, C	3/20/2020	04/06/2020	Biotek Remedys	MD-01
40	39	00944270004	GAMMAGARD LIQUID	1,100	14,639.94	0.00	731.99	M, S.2	11/10/2017	11/15/2017	Biotek Remedys	MD-01
41	40	00944270004	GAMMAGARD LIQUID	1,100	14,639.94	0.00	731.99	M, S.2	12/11/2017	12/20/2017	Biotek Remedys	MD-01
42	41	13533080020	GAMUNEX-C	1,400	14,535.44	0.00	726.77	M, L	2/21/2017	03/20/2017	Biotek Remedys	MD-01
43	42	13533080024	GAMUNEX-C	1,400	14,535.44	0.00	726.77	M, L	3/17/2017	04/12/2017	Biotek Remedys	MD-01
44	43	00944270004	GAMMAGARD LIQUID	1,000	14,523.07	0.00	726.15	B, G	4/12/2019	04/16/2019	Biotek Remedys	MD-01
45	44	68982085002	OCTAGAM	900	14,453.66	0.00	722.68	S, C	11/11/2019	03/06/2020	Biotek Remedys	MD-01
46	45	68982085002	OCTAGAM	900	14,453.66	0.00	722.68	S, C	12/2/2019	03/06/2020	Biotek Remedys	MD-01
47	46	44206043820	PRIVIGEN	1,000	14,379.74	8,370.26	4,925.38	P, S	6/2/2016	09/21/2017	Biotek Remedys	MD-01
48	47	00069122402	PANZYGA	750	14,347.38	0.00	717.36	W, S	3/3/2020	03/10/2020	Biotek Remedys	MD-01
49	48	00069122402	PANZYGA	750	14,347.38	0.00	717.36	W, S	4/2/2020	04/07/2020	Biotek Remedys	MD-01
50	49	00069122402	PANZYGA	750	14,347.38	0.00	717.36	W, S	4/21/2020	04/28/2020	Biotek Remedys	MD-01
51	50	00069122402	PANZYGA	750	14,347.38	0.00	717.36	W, S	5/13/2020	05/20/2020	Biotek Remedys	MD-01
52	51	68982085002	OCTAGAM	900	14,292.12	0.00	714.61	S, C	10/11/2019	03/06/2020	Biotek Remedys	MD-01
53	52	00944270004	GAMMAGARD LIQUID	1,000	14,278.35	0.00	713.92	B, G	10/31/2018	11/07/2018	Biotek Remedys	MD-01
54	53	00944270004	GAMMAGARD LIQUID	1,000	14,278.35	0.00	713.92	B, G	11/26/2018	12/07/2018	Biotek Remedys	MD-01
55	54	00944270004	GAMMAGARD LIQUID	1,000	14,278.35	0.00	713.92	B, G	12/17/2018	12/25/2018	Biotek Remedys	MD-01
56	55	68982084004	OCTAGAM	3,000	14,273.63	5,647.70	3,149.22	H, M	8/25/2016	10/12/2016	Biotek Remedys	MD-01
57	56	68982084003	OCTAGAM	1,800	14,048.98	0.00	702.45	S, C	5/30/2019	03/06/2020	Biotek Remedys	MD-01
58	57	13533080024	GAMUNEX-C	1,200	14,033.56	0.00	701.68	M, R	2/19/2020	02/26/2020	Biotek Remedys	MD-01
59	58	13533080024	GAMUNEX-C	1,200	14,033.56	0.00	701.68	M, R	3/19/2020	03/25/2020	Biotek Remedys	MD-01
60	59	13533080024	GAMUNEX-C	1,200	14,033.56	0.00	701.68	M, R	4/15/2020	04/22/2020	Biotek Remedys	MD-01
61	60	13533080024	GAMUNEX-C	1,200	14,033.56	0.00	701.68	M, R	5/12/2020	05/20/2020	Biotek Remedys	MD-01
62	61	76125090050	GAMMAKED	950	13,633.23	0.00	681.66	Q, J	4/2/2020	05/21/2020	Biotek Remedys	MD-01

Final Exhibit II

	A	B	C	D	E	F	G	H	I	J	K	L
1	**Sample False Claim No.**	**NDC Code**	**NDC Code Description**	**QTY Dispensed**	**Amt Above OOPT**	**Amt Below OOPT**	**Amt Pd Bene POS**	**Beneficiary**	**Date From Hdr**	**Date Processed**	**Pharm Name**	**Presc IDs**
63	62	76125090050	GAMMAKED	950	13,633.23	0.00	681.66	Q, J	5/13/2020	05/21/2020	Biotek Remedys	MD-01
64	63	68982084004	OCTAGAM	1,800	13,508.70	0.00	675.44	S, C	3/7/2019	03/06/2020	Biotek Remedys	MD-01
65	64	68982084004	OCTAGAM	1,800	13,508.70	0.00	675.44	S, C	4/18/2019	03/06/2020	Biotek Remedys	MD-01
66	65	76125090050	GAMMAKED	950	13,471.69	0.00	0.00	Q, J	11/21/2019	03/06/2020	Biotek Remedys	MD-01
67	66	00069131202	PANZYGA	800	13,418.86	0.00	60.00	R, M	10/9/2019	10/15/2019	Biotek Remedys	MD-01
68	67	00069141502	PANZYGA	800	13,418.86	0.00	60.00	R, M	11/20/2019	11/26/2019	Biotek Remedys	MD-01
69	68	00069141502	PANZYGA	800	13,418.86	0.00	60.00	R, M	12/16/2019	12/24/2019	Biotek Remedys	MD-01
70	69	76125090050	GAMMAKED	950	13,046.28	0.00	652.31	Q, J	2/20/2020	05/21/2020	Biotek Remedys	MD-01
71	70	00069131202	PANZYGA	800	13,028.43	0.00	60.00	R, M	4/8/2020	04/14/2020	Biotek Remedys	MD-01
72	71	00069141502	PANZYGA	800	12,960.80	67.63	60.00	R, M	3/19/2020	03/25/2020	Biotek Remedys	MD-01
73	72	68982085004	OCTAGAM	800	12,676.11	0.00	633.81	S, K	1/30/2019	02/04/2019	Biotek Remedys	MD-01
74	73	68982085003	OCTAGAM	800	12,676.11	0.00	633.81	S, K	2/26/2019	03/05/2019	Biotek Remedys	MD-01
75	74	68982085004	OCTAGAM	800	12,676.11	0.00	633.81	S, K	3/27/2019	04/02/2019	Biotek Remedys	MD-01
76	75	76125090050	GAMMAKED	950	12,554.98	0.00	0.00	Q, J	10/11/2019	03/06/2020	Biotek Remedys	MD-01
77	76	00069131202	PANZYGA	700	12,322.31	0.00	250.00	L, E	3/19/2020	03/26/2020	Biotek Remedys	MD-01
78	77	00069131202	PANZYGA	700	12,322.31	0.00	250.00	L, E	4/30/2020	05/07/2020	Biotek Remedys	MD-01
79	78	00069131202	PANZYGA	700	12,270.72	0.00	250.00	L, E	2/19/2020	02/20/2020	Biotek Remedys	MD-01
80	79	00069131202	PANZYGA	700	12,228.89	0.00	250.00	L, E	11/7/2019	11/14/2019	Biotek Remedys	MD-01
81	80	00069131202	PANZYGA	700	12,228.89	0.00	250.00	L, E	11/25/2019	11/27/2019	Biotek Remedys	MD-01
82	81	68982085004	OCTAGAM	800	12,222.59	0.00	611.13	S, K	11/6/2018	11/13/2018	Biotek Remedys	MD-01
83	82	68982085004	OCTAGAM	800	12,222.59	0.00	611.13	S, K	12/4/2018	12/13/2018	Biotek Remedys	MD-01
84	83	68982084004	OCTAGAM	1,600	12,214.02	0.00	610.70	S, K	8/16/2018	08/22/2018	Biotek Remedys	MD-01
85	84	68982084004	OCTAGAM	1,600	12,214.02	0.00	610.70	S, K	9/12/2018	09/18/2018	Biotek Remedys	MD-01
86	85	68982084004	OCTAGAM	1,600	12,214.02	0.00	610.70	S, K	10/10/2018	10/16/2018	Biotek Remedys	MD-01
87	86	00069110902	PANZYGA	700	12,202.39	0.00	250.00	L, E	5/20/2020	05/21/2020	Biotek Remedys	MD-01
88	87	44206043710	PRIVIGEN	1,500	12,122.02	7,677.98	3,435.89	B, J	8/8/2017	08/21/2017	Biotek Remedys	MD-01
89	88	44206043710	PRIVIGEN	800	11,990.84	0.00	599.54	H, J	4/30/2020	05/04/2020	Biotek Remedys	MD-01
90	89	68982084004	OCTAGAM	3,000	11,859.66	9,070.44	2,844.65	R, J	4/21/2017	04/25/2017	Biotek Remedys	MD-01
91	90	68982085002	OCTAGAM	900	11,171.73	0.00	558.58	S, C.2	12/6/2019	12/10/2019	Biotek Remedys	MD-01
92	91	68982085002	OCTAGAM	900	11,171.73	0.00	558.58	S, C.2	12/26/2019	12/31/2019	Biotek Remedys	MD-01
93	92	13533080020	GAMUNEX-C	1,750	11,153.68	7,459.58	3,298.06	A, L	6/29/2017	02/25/2020	Biotek Remedys	MD-01
94	93	68982084003	OCTAGAM	1,400	10,539.77	0.00	526.98	G, D	7/11/2018	07/18/2018	Biotek Remedys	MD-01
95	94	68982085002	OCTAGAM	700	10,539.77	0.00	526.98	G, D	10/26/2018	10/30/2018	Biotek Remedys	MD-01
96	95	68982084001	OCTAGAM	1,400	10,539.53	0.00	526.97	G, D	10/3/2018	10/09/2018	Biotek Remedys	MD-01
97	96	68982084004	OCTAGAM	1,400	10,532.38	0.00	526.61	G, D	4/12/2018	04/17/2018	Biotek Remedys	MD-01
98	97	13533080071	GAMUNEX-C	1,400	10,522.45	4,012.99	2,131.31	M, L	1/25/2017	03/01/2017	Biotek Remedys	MD-01
99	98	68982084003	OCTAGAM	1,400	10,233.01	0.00	511.65	G, D	1/24/2018	01/30/2018	Biotek Remedys	MD-01
100	99	68982084003	OCTAGAM	1,400	10,233.01	0.00	511.65	G, D	2/14/2018	02/20/2018	Biotek Remedys	MD-01
101	100	68982084003	OCTAGAM	1,400	10,233.01	0.00	511.65	G, D	3/19/2018	03/27/2018	Biotek Remedys	MD-01
102												
103				128,760	1,562,846.38	95,284.93	103,682.23					

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, *ex rel.* SHANTAE M. WYATT & LATOYA SPARROW,	:	
Plaintiffs,	:	
	:	
v.	:	**Civ. No. 19-6069**
	:	
BIOTEK REMEDYS, INC. *et al.*,	:	
Defendants.	:	

O R D E R

AND NOW, upon consideration of the Government's Notice of Election to Intervene (Doc. No. 19) and Response (Doc. No. 21), it is hereby **ORDERED** that the Government serve its Complaint upon Defendants, together with this Order, within 60 days.

AND IT IS SO ORDERED.

/s/ Paul S. Diamond

Paul S. Diamond, J.